Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

COMPARISON OF FOURTH-QUARTER 2005 AVERAGE SALES PRICES TO AVERAGE MANUFACTURER PRICES: IMPACT ON MEDICARE REIMBURSEMENT FOR SECOND QUARTER 2006

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EXECUTIVE SUMMARY

OBJECTIVE

To determine (1) whether average sales prices (ASP) for individual Medicare Part B prescription drugs exceeded average manufacturer prices (AMP) by at least 5 percent during the fourth quarter of 2005 and (2) the impact of lowering reimbursement amounts for drugs that meet the 5-percent threshold.

BACKGROUND

In 2005, Medicare Part B began paying for most covered drugs using a new methodology based on ASPs. Section 1847A(c) of the Social Security Act (the Act) defines an ASP as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions. Manufacturers report ASPs by national drug codes (NDC) and must provide the Centers for Medicare & Medicaid Services (CMS) with the ASP and volume of sales for each of their NDCs on a quarterly basis.

Although manufacturers submit ASP data by NDCs, CMS does not reimburse Medicare providers for drugs using NDCs. Instead, CMS uses Healthcare Common Procedure Coding System (HCPCS) codes. More than one NDC may meet the definition of a particular HCPCS code; therefore, CMS uses NDC-level information submitted by the manufacturers to calculate an ASP for each covered HCPCS code. When CMS calculates payment amounts for HCPCS codes, it must weight ASPs at the NDC level by the amount of the drug sold during the quarter. Under the ASP pricing methodology, Medicare's allowance for most Part B drug codes is equal to 106 percent of the volume-weighted ASPs for those HCPCS codes.

Section 1847A(d)(2)(B) of the Act mandates that OIG compare ASPs with AMPs. As defined in section 1927(k)(1) of the Act, an AMP is the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, minus customary prompt pay discounts. As part of the Medicaid drug rebate program, manufacturers must provide CMS with the AMP for each of their NDCs on a quarterly basis, pursuant to section 1927(b)(3) of the Act. If the ASP for a drug exceeds the AMP by at least 5 percent, section 1847A(d)(3)(A) of the Act grants the Secretary

of the Department of Health and Human Services authority to disregard the ASP pricing methodology for that drug. Consistent with section 1847A(d)(3)(C) of the Act, the payment amount for the drug code may then be replaced with the lesser of the widely available market price for the drug (if any) or 103 percent of the AMP.

For this inspection, we obtained CMS's ASP data from the fourth quarter of 2005, which were used to establish volume-weighted ASPs and reimbursement amounts for the second quarter of 2006. We also obtained CMS's AMP data from the fourth quarter of 2005. We used these AMP data to calculate volume-weighted AMPs using the same method that CMS uses to calculate volume-weighted ASPs. Ultimately, we compared volume-weighted ASPs to volume-weighted AMPs for 341 HCPCS codes, and identified codes for which ASPs exceeded AMPs by at least 5 percent.

FINDING

For 46 of 341 HCPCS codes reviewed, the volume-weighted ASP exceeded the volume-weighted AMP by at least 5 percent. Based on our analysis of data from the fourth quarter of 2005, a total of 46 HCPCS codes had an ASP that exceeded the AMP by at least 5 percent. For 13 of the 46 HCPCS codes, volume-weighted ASPs exceeded volume-weighted AMPs by at least 20 percent, with ASPs for 4 of these exceeding AMPs by more than 50 percent. If reimbursement amounts for these 46 codes had been based on 103 percent of the AMP during the second quarter of 2006, we estimate that Medicare expenditures would have been reduced by $16 million.

SUMMARY

For the purpose of monitoring new Medicare reimbursement amounts based on ASPs, and consistent with sections 1847A(d)(2)(B) and 1847A(d)(3) of the Act, OIG compared ASPs to AMPs to identify instances in which the ASP for a particular drug exceeded the AMP by a threshold of 5 percent. This review is the second of such comparisons, and we identified 46 HCPCS codes that are eligible for price adjustment under authority of the Secretary. Twenty of the 46 HCPCS codes were previously eligible for price adjustment as a result of OIG's first comparison between ASPs and AMPs, which was performed using data from the third quarter of 2004.

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BACKGROUND

Medicare Part B Coverage of Prescription Drugs

Medicare Part B covers only a limited number of outpatient prescription drugs. Covered drugs include injectable drugs administered by a physician; certain self-administered drugs, such as oral anticancer drugs and immunosuppressive drugs; drugs used in conjunction with durable medical equipment; and some vaccines.

Medicare Part B Payments for Prescription Drugs

The Centers for Medicare & Medicaid Services (CMS) contracts with private companies, known as carriers, to process and pay Medicare Part B claims, including those for prescription drugs. Claims for drugs that are used with medical equipment are typically processed by one of four durable medical equipment regional carriers. Claims for other types of covered drugs are processed by local carriers. To obtain reimbursement for covered outpatient prescription drugs, physicians and suppliers submit claims using procedure codes. CMS established the Healthcare Common Procedure Coding System (HCPCS) to provide a standardized coding system for describing the specific items and services provided in the delivery of health care. In the case of prescription drugs, each HCPCS code defines the drug name and dosage size but does not specify manufacturer or package size information.

Medicare and its beneficiaries spent almost $10 billion for Part B drugs in 2005. Although Medicare paid for almost 550 outpatient prescription drug HCPCS codes that year, the majority of spending for Part B drugs was concentrated on a relatively small subset of those codes. In 2005, 52 codes represented 90 percent of the expenditures for Part B drugs, with only 11 of these drugs representing half of the total Part B drug expenditures.

INTRODUCTION

Reimbursement Methodology for Part B Drugs and Biologicals

In 2005, Medicare Part B began paying for most covered drugs using an entirely new methodology based on ASPs.[1] Section 1847A(c) of the Social Security Act (the Act), as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), P.L. 108-173, defines an ASP as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions such as volume discounts, prompt pay discounts, and cash discounts; free goods contingent on purchase requirements; chargebacks; and rebates other than those obtained through the Medicaid drug rebate program.[2] Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" in the Medicaid drug rebate program.[3,4]

Manufacturers report ASPs by national drug codes (NDC), which are 11-digit identifiers that indicate the manufacturer of the drug, the product dosage form, and the package size. Manufacturers must provide CMS with the ASP and volume of sales for each NDC on a quarterly basis, with submissions due 30 days after the close of each quarter.[5]

Given that Medicare Part B reimbursement for outpatient drugs is based on HCPCS codes rather than NDCs, and that more than one NDC may meet the definition of a particular HCPCS code, CMS has developed a file that "crosswalks" manufacturers' NDCs to HCPCS codes. CMS uses information in this crosswalk to calculate volume-weighted ASPs for covered HCPCS codes.

Fourth-quarter 2005 ASP submissions from manufacturers served as the basis for second-quarter 2006 Medicare allowances for most covered

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[1] For 2004, the reimbursement amount for most covered drugs was based on 85 percent of the average wholesale price (AWP) as published in national pricing compendia such as the "Red Book." Prior to 2004, Medicare Part B reimbursed for covered drugs based on the lower of either the billed amount or 95 percent of the AWP.

[2] Section 1847A(c)(3) of the Act.

[3] Pursuant to section 1927(c)(1)(C)(i) of the Act, "best price" is the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, with certain exceptions.

[4] Section 1847A(c)(2) of the Act.

[5] Section 1927(b)(3) of the Act.

drug codes. Under the ASP pricing methodology, the Medicare allowance for most Part B drugs is equal to 106 percent of the ASP for the HCPCS code. Medicare beneficiaries are responsible for 20 percent of this amount in the form of coinsurance.

The Medicaid Drug Rebate Program and AMP

For Federal payment to be available for covered outpatient drugs provided under Medicaid, sections 1927(a)(1) and (b)(1) of the Act mandate that drug manufacturers enter into rebate agreements with the Secretary of the Department of Health and Human Services and pay quarterly rebates to State Medicaid agencies. Under these rebate agreements, and pursuant to section 1927(b)(3) of the Act, manufacturers must provide CMS with the AMP for each of their NDCs on a quarterly basis. As defined in section 1927(k)(1) of the Act, the AMP is the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, minus customary prompt pay discounts. The AMP is calculated as a weighted average of prices for all of a manufacturer's package sizes of a drug sold during a given quarter, and is reported for the lowest identifiable quantity of the drug (e.g., 1 milligram, 1 milliliter, 1 tablet, 1 capsule).

Office of Inspector General's Monitoring of ASP and AMP

Section 1847A(d)(2)(B) of the Act mandates that the Office of Inspector General (OIG) compare ASPs with AMPs. If the ASP for a drug exceeds the AMP by at least 5 percent, section 1847A(d)(3) of the Act grants the Secretary authority to disregard the ASP pricing methodology for that drug. Consistent with section 1847A(d)(3)(C) of the Act, the payment amount for the drug code may then be replaced with the lesser of the widely available market price for the drug (if any) or 103 percent of the AMP.

In April 2006, OIG released the first of its reports comparing ASPs to AMPs. The study, entitled "Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Prices to Average Manufacturer Prices" (OEI-03-04-00430), identified a number of HCPCS codes with ASPs that exceeded AMPs by at least 5 percent in the third quarter of 2004. Overall, CMS indicated that the information in the report is helpful in its continuing efforts to monitor payment adequacy under the ASP methodology. However, CMS noted that OIG's review was conducted using data submitted during the initial implementation phase of the ASP methodology. Although CMS acknowledged the Secretary's authority to adjust ASP payment limits when certain conditions are

met, it believes that other issues should be considered, including the timing and frequency of pricing comparisons, stabilization of ASP reporting, the effective date and duration of rate substitution, and the accuracy of ASP and AMP data.

Related Work by the Office of Inspector General

In a February 2006 report entitled "Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs" (OEI-03-05-00310), OIG stated that CMS's method for calculating volume-weighted ASPs is incorrect because CMS does not use billing units consistently throughout its equation. As a result, many HCPCS codes have a reimbursement amount that is higher or lower than the amount that would have been calculated if billing units were used consistently. OIG recommended that CMS change its calculation of volume-weighted ASPs. Although CMS indicated that it may consider altering the ASP methodology, it has yet to do so.

In September 2005, OIG issued a report in response to section 303(c)(3) of the MMA, which mandated that OIG determine whether physician practices in the specialties of hematology, hematology/oncology, and medical oncology could obtain drugs and biologicals for the treatment of cancer patients at 106 percent of the ASP. According to this report, "Adequacy of Medicare Part B Drug Reimbursement to Physician Practices for the Treatment of Cancer Patients" (A-06-05-00024), physician practices in these specialties could generally purchase drugs for the treatment of cancer patients at or below the reimbursement rate established under the ASP payment methodology.

METHODOLOGY

We obtained CMS's NDC-level ASP data from the fourth quarter of 2005, which were used to establish Part B drug reimbursement amounts for the second quarter of 2006. In addition, we obtained the file that CMS used to crosswalk NDCs to their corresponding HCPCS codes. Both the ASP data and the crosswalk file were updated as of March 2006. We also obtained AMP data from CMS for the fourth quarter of 2005.

Calculation of Volume-Weighted Average Sales Price

As mentioned previously, Medicare does not base reimbursement for covered drugs on NDCs; instead, it uses HCPCS codes. Therefore, CMS uses ASP information submitted by manufacturers for each NDC to calculate a volume-weighted ASP for each covered HCPCS code. When

calculating these volume-weighted ASPs, CMS only includes NDCs with ASP submissions that are deemed valid. We did not examine the NDCs that CMS opted to exclude from its calculation, nor did we verify the accuracy of CMS's crosswalk files.

As of March 2006, CMS had established prices for 496 HCPCS codes based on the ASP reimbursement methodology. Reimbursement amounts for the 496 HCPCS codes were based on ASP data for 3,061 NDCs.

To calculate the volume-weighted ASPs for these 496 codes, CMS used an equation that involves the following variables: the ASP for the NDC as reported by the manufacturer, the volume of sales for the NDC as reported by the manufacturer, and the number of billing units in the NDC as determined by CMS. The amount of the drug contained in an NDC may differ from the amount of the drug specified by the HCPCS code that providers use to bill Medicare. Therefore, the number of billing units in an NDC describes the number of HCPCS code units that are in that NDC. For instance, an NDC may contain a total of 10 milliliters of Drug A, but the corresponding HCPCS code may be defined as only 5 milliliters of Drug A. In this case, there are two billing units in the NDC. CMS calculates the number of billing units in each 11-digit NDC when developing its crosswalk files. A more detailed description of CMS's method of calculating volume-weighted ASPs is provided in Appendix A.

Analysis of Average Manufacturer Price Data

An AMP is reported for the lowest identifiable quantity of the drug contained in the NDC (e.g., 1 milligram, 1 milliliter, 1 tablet, 1 capsule). In contrast, an ASP is reported for the entire amount of the drug contained in the NDC (e.g., for 50 milliliters, for 100 tablets). To ensure that the AMP would be comparable to the ASP, it was necessary to convert the AMP for each NDC so that it represented the total amount of the drug contained in that NDC.

In making these conversions, we examined AMPs only for those 3,061 NDCs that CMS used in its calculation of volume-weighted ASPs for the 496 codes. If AMP data were not available for one or more of these NDCs, we excluded the corresponding HCPCS code from our analysis. We excluded a total of 144 HCPCS codes using this conservative approach. The remaining 352 HCPCS codes had AMP data for every NDC that CMS used in its calculation of volume-weighted ASPs. These 352 HCPCS codes represented 1,659 NDCs.

We then multiplied the AMPs for these 1,659 NDCs by the total amount of the drug contained in each NDC, as identified by sources such as the CMS crosswalk file, the "Red Book," manufacturer Web sites, and the Food and Drug Administration's NDC directory. We will refer to the resulting amounts as converted AMPs. For 23 NDCs, we could not successfully identify the amount of the drug reflected by the ASP and therefore could not calculate a converted AMP. These 23 NDCs were crosswalked to 11 HCPCS codes. We did not include these 11 HCPCS codes (126 NDCs) in our final analysis.

Using the converted AMPs for the remaining 1,533 NDCs, we then calculated volume-weighted AMPs for each of the codes using the same method that CMS uses to calculate volume-weighted ASPs. We calculated volume-weighted AMPs for a total of 341 HCPCS codes. We did not verify the accuracy of manufacturer-reported ASP and AMP data.

Comparing Volume-Weighted ASPs to Volume-Weighted AMPs

For each of the 341 HCPCS codes included in our study, we then compared the volume-weighted ASPs and AMPs and identified codes with ASPs that exceeded AMPs by at least 5 percent.

For those HCPCS codes that met or exceeded the 5-percent threshold, we conducted a review of the associated NDCs to verify the accuracy of the billing units information. According to our review, four of the codes that met the 5-percent threshold had associated NDCs with potentially inaccurate billing units.[6] Given that volume-weighted ASPs and AMPs were calculated using this billing unit information, we could not be certain that the results for these four codes were correct. Therefore, we did not include these four codes in our findings.

For the remaining HCPCS codes, we then estimated the monetary impact of lowering reimbursement to 103 percent of the AMP.[7] First we

[6] NDCs for these four codes had billing unit information in CMS's crosswalk file that may not have accurately reflected the number of billing units actually contained in the NDC.

[7] Pursuant to section 1847A(d)(3) of the Act, if the ASP for a drug exceeds the AMP by at least 5 percent, the Secretary has authority to disregard the ASP pricing methodology for that drug. Consistent with section 1847A(d)(3)(C) of the Act, the payment amount for the drug code may then be replaced with the lesser of the widely available market price for the drug (if any) or 103 percent of the AMP. For the purposes of this study, we used 103 percent of the AMP to estimate the impact of lowering reimbursement amounts. If widely available market prices had been available for these drugs and lower than 103 percent of the AMP, the savings estimate presented in this report would have been greater.

calculated 103 percent of the volume-weighted AMP and subtracted this amount from the second-quarter 2006 reimbursement amount for the HCPCS code, which is equal to 106 percent of the volume-weighted ASP. To estimate the financial effect for second quarter 2006, we then multiplied the difference by one-fourth of the number of services that were allowed by Medicare for each HCPCS code in 2005, as reported in CMS's Part B Extract and Summary System (BESS).[8] This estimate assumes that the number of services that were allowed by Medicare in 2005 remained consistent from one quarter to the next, and that there were no significant changes in utilization in 2006.

This study was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

[8] At the time of extraction, BESS data were 98 percent complete.

FINDING

For 46 of 341 HCPCS codes reviewed, the volume-weighted ASP exceeded the volume-weighted AMP by at least 5 percent

Consistent with sections 1847A(d)(2)(B) and 1847A(d)(3) of the Act, OIG compared ASPs to AMPs to identify instances in which the ASP for a particular drug exceeded the AMP by a threshold of 5 percent. Forty-six of the 341 HCPCS codes included in our comparison met or surpassed this 5-percent threshold in the fourth quarter of 2005. Of these 46 HCPCS codes, 20 were identified in a previous OIG report as having ASPs that exceeded AMPs by at least 5 percent in the third quarter of 2004.[9] A list of all 46 HCPCS codes is presented in Appendix B.

Table 1 below describes the extent to which ASPs exceeded AMPs for the 46 HCPCS codes. For 13 of the 46 codes, volume-weighted ASPs exceeded volume-weighted AMPs by at least 20 percent, with ASPs for 4 of these exceeding AMPs by more than 50 percent.[10]

Table 1: Extent to Which ASPs Exceeded AMPs for 46 HCPCS Codes

Percentage Difference Between ASP and AMP	Number of HCPCS Codes
5–9%	14
10–19%	19
20–29%	5
30–39%	1
40–49%	3
50–59%	1
60–69%	0
70–79%	0
80–89%	2
90–99%	1
Total	**46**

Source: OIG analysis of fourth-quarter 2005 ASP and AMP data, 2006.

[9] This report, "Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Price to Average Manufacturer Price" (OEI-03-04-00430), found that 51 HCPCS codes met the 5-percent threshold when CMS's method was used to calculate volume-weighted ASPs and AMPs using data from the third quarter of 2004.

[10] Due to the confidential nature of ASP and AMP data, OIG is not publicly providing the exact percentages for each of the 46 HCPCS codes. However, OIG will provide CMS with detailed information regarding the codes identified in this report.

F I N D I N G

Lowering reimbursement amounts for these 46 HCPCS codes to 103 percent of the average manufacturer price would have reduced Medicare allowances by an estimated $16 million in the second quarter of 2006.

Sections 1847A(d)(3)(A) and (B) of the Act grant the Secretary authority to disregard the ASP pricing methodology for a drug with an ASP that exceeds the AMP by at least 5 percent. If that criterion is met, the Secretary has authority to lower the reimbursement amount for the drug to 103 percent of the AMP.[11] In this study, we identified 46 HCPCS codes that met or exceeded the 5-percent threshold specified in the Act. If reimbursement amounts for these 46 codes had been based on 103 percent of AMP during the second quarter of 2006, we estimate that Medicare expenditures would have been reduced by $16 million.[12]

Three of the 46 HCPCS codes accounted for almost 80 percent of the $16 million. If the reimbursement amounts for these 3 codes had been based on 103 percent of the AMP during the second quarter of 2006, Medicare expenditures would have been reduced by an estimated $13 million.

[11] Consistent with section 1847A(d)(3)(C) of the Act, the payment amount for the drug code may then be replaced with the lesser of the widely available market price for the drug (if any) or 103 percent of the AMP. For the purposes of this study, we used 103 percent of the AMP to estimate the impact of lowering reimbursement amounts. If widely available market prices had been available for these drugs and lower than 103 percent of the AMP, the savings estimate presented in this report would have been greater.

[12] This estimate is based on one-fourth of the number of services allowed by Medicare for each HCPCS code in 2005.

SUMMARY

For the purpose of monitoring new Medicare reimbursement amounts based on ASPs, and consistent with sections 1847A(d)(2)(B) and 1847A(d)(3) of the Act, OIG compared ASPs to AMPs to identify instances in which the ASP for a particular drug exceeded the AMP by a threshold of 5 percent. This review is the second of such comparisons, and we identified 46 HCPCS codes that are eligible for price adjustment under authority of the Secretary. Twenty of the forty-six HCPCS codes were previously eligible for price adjustment as a result of OIG's first comparison between ASPs and AMPs, which was performed using data from the third quarter of 2004.

APPENDIX - A

Equation Used by the Centers for Medicare & Medicaid Services to Calculate Volume-Weighted Average Sales Prices

In the following equation, a "unit" is defined as the entire amount of the drug contained in the National Drug Code (NDC):

$$\text{Volume-Weighted ASP for the Billing Unit of HCPCS Code} = \frac{\text{Sum of } \left[\frac{\text{ASP for NDC}}{\text{Billing Units in NDC}} * \text{Number of NDCs Sold} \right]}{\text{Sum of Number of NDCs Sold}}$$

CMS's calculation of volume-weighted ASPs is discussed in greater detail in the Office of Inspector General (OIG) report, "Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs" (OEI-03-05-00310). This report found that CMS's method for calculating volume-weighted ASPs is incorrect because CMS does not use billing units consistently throughout its equation. Therefore, OIG recommended that CMS adopt an alternate method for calculating volume-weighted ASPs.

APPENDIX - B

Forty-Six HCPCS Codes With an ASP That Exceeded the AMP by at Least 5 Percent

Code	Description
J0207	Injection, amifostine, 500 mg
J0360*	Injection, hydralazine HCl, up to 20 mg
J0470*	Injection, dimercaprol, per 100 mg
J0610	Injection, calcium gluconate, per 10 mL
J0640	Injection, leucovorin calcium, per 50 mg
J0694	Injection, cefoxitin sodium, 1 g
J0720	Injection, chloramphenicol sodium succinate, up to 1 g
J0745	Injection, codeine phosphate, per 30 mg
J1230	Injection, methadone HCl, up to 10 mg
J1240*	Injection, dymenhydrinate, up to 50 mg
J1270	Injection, doxercalciferol, 1 mcg
J1460*	Injection, gamma globulin, intramuscular, 1 cc
J1470*	Injection, gamma globulin, intramuscular, 2 cc
J1480*	Injection, gamma globulin, intramuscular, 3 cc
J1490*	Injection, gamma globulin, intramuscular, 4 cc
J1500*	Injection, gamma globulin, intramuscular, 5 cc
J1510*	Injection, gamma globulin, intramuscular, 6 cc
J1520*	Injection, gamma globulin, intramuscular, 7 cc
J1530*	Injection, gamma globulin, intramuscular, 8 cc
J1540*	Injection, gamma globulin, intramuscular, 9 cc
J1550*	Injection, gamma globulin, intramuscular, 10 cc
J1560*	Injection, gamma globulin, intramuscular, over 10 cc
J1670	Injection, tetanus immune globulin, human, up to 250 units
J1850	Injection, kanamycin sulfate, up to 75 mg
J2545*	Pentamidine isethionate, inhalation solution, per 300 mg
J2690*	Injection, procainamide HCl, up to 1 g
J2720	Injection, protamine sulfate, per 10 mg
J3000	Injection, streptomycin, up to 1 g
J3120	Injection, testosterone enanthate, up to 100 mg
J3130	Injection, testosterone enanthate, up to 200 mg
J3410*	Injection, hydroxyzine HCl, up to 25 mg
J3411	Injection, thiamine HCl, 100 mg
J3420*	Injection, vitamin B-12 cyanocobalamin, up to 1,000 mcg
J3475	Injection, magnesium sulfate, per 500 mg
J7501	Azathioprine, parenteral, 100 mg
J7620	Albuterol, up to 2.5 mg and ipratropium bromide, up to 0.5 mg, noncompounded inhalation solution, administered through DME
J7638	Dexamethasone, inhalation solution administered through DME, unit dose form, per mg

A P P E N D I X ~ B

Code	Description
J9000	Doxorubicin HCl, 10 mg
J9130	Dacarbazine, 100 mg
J9140	Dacarbazine, 200 mg
J9190	Fluorouracil, 500 mg
J9202*	Goserelin acetate implant, per 3.6 mg
J9211	Idarubicin HCl, 5 mg
J9214	Interferon, alfa-2b, recombinant, 1 million units
J9340	Thiotepa, 15 mg
J9360*	Vinblastine sulfate, 1 mg

*Codes marked with an asterisk were identified in a previous OIG report as having ASPs that exceeded AMPs by at least 5 percent in the third quarter of 2004.

Source: OIG analysis of fourth-quarter 2005 ASP and AMP data, 2006.

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OIG Targets 46 Part B Physician-Administered Drugs For Possible Rate Cut, Based On ASP Versus AMP Prices

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A downward payment adjustment could be in store for selected drugs administered in the physician's office and reimbursed under Medicare Part B, if the Centers for Medicare & Medicaid Services acts on the findings of a recent inspection report by the HHS Office of Inspector General.

According to the report. released July 20, 46 HCPCS (Healthcare Common Procedure Coding System) codes are being overpaid, based on a comparison of average sales prices (ASPs), now used to calculate Part B drug payments, and average manufacturer prices (AMPs). Drugs on the list include dacarbazine (J9130 and 9140), albuterol (J7620), streptomycin (J3000), methadone (J1230) and vitamin injections (J3411 and J3420).

e agency reviewed 341 HCPCS codes and found that ASPs for 46 exceeded their AMPs by at least 5%. Thirteen of these exceeded AMPs by more than 20%, and for four exceeded AMPs by more than 50%. OIG did not give exact percentages for each of the 46 services in the report; but it is passing them on to CMS and Congress, it said in a footnote.

Further, 20 of the 46 HCPCS codes in the latest report were already identified for a possible rate adjustment based on an earlier OIG study, which used data from 2004, the Inspector General notes. That study, released in April, also compared ASPs to AMPs (see story, *Medicare Drug Focus*, May 8, 2006).

Of the 20 drugs that appeared in both reports, 10 are gamma globulin intramuscular injections (J1460 through J1560) in different doses. HCPCS is the coding system used to bill drugs to Medicare.

ASP is derived by dividing dollar sales of a drug - net of any price concessions such as discounts, rebates and samples - by the number of units sold in a quarter. OIG derives AMP from prices that wholesalers pay for drugs distributed to retail pharmacies, taking into account prompt pay discounts.

OIG analyses of ASPs versus AMPs is part of a congressional mandate to narrow the differential between ASP and AMP. The Medicare Modernization Act requires these studies to see whether CMS is overpaying for Part B drugs administered in the outpatient setting.

If the ASP for a product exceeds AMP by 5% or more, CMS is authorized to substitute a different reimbursement rate: either AMP plus 3% or the "widely available market price," whichever is less.

edicare had paid AMP plus 3% for the 46 drugs identified, it would have saved $16 mil. in the second quarter of 2006, the report states.

other recent report identified five Part B drugs whose ASPs diverged from widely available market prices(see story, *Medicare Drug Focus*, July 3, 2006).

-Todd Leeuwenburgh

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MONITORING MEDICARE PART B DRUG PRICES: A COMPARISON OF AVERAGE SALES PRICES TO AVERAGE MANUFACTURER PRICES

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EXECUTIVE SUMMARY

OBJECTIVE

To determine whether average sales prices (ASP) for individual Medicare Part B prescription drugs exceed average manufacturer prices (AMP) by at least 5 percent.

BACKGROUND

Expenditures for Medicare Part B drugs have tripled over the past several years, increasing from approximately $3.3 billion in 1998 to over $10 billion in 2004. In 2005, Medicare Part B began paying for most covered drugs using a new methodology based on ASPs. Manufacturers report ASPs by national drug code (NDC) and must provide the Centers for Medicare & Medicaid Services (CMS) with the ASP and volume of sales for each of their NDCs on a quarterly basis.[1]

Although manufacturers submit ASP data by NDCs, CMS does not reimburse Medicare providers for drugs using NDCs. Instead, CMS uses Healthcare Common Procedure Coding System (HCPCS) codes.[2] More than one NDC may meet the definition of a particular HCPCS code; therefore, CMS uses NDC-level information submitted by the manufacturers to calculate an ASP for each covered HCPCS code. When CMS calculates payment amounts for HCPCS codes, it must weight ASPs at the NDC level by the amount of the drug sold during the quarter. Under the ASP pricing methodology, Medicare's allowance for most Part B drug codes is equal to 106 percent of the volume-weighted ASPs for those HCPCS codes.

However, according to a recent Office of Inspector General (OIG) report entitled "Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs" (OEI-03-05-00310), the way that CMS calculates a volume-weighted ASP is incorrect. In that report, we proposed an alternate method for calculating a volume-weighted ASP and recommended that CMS adopt this alternate method for calculating volume-weighted ASP.

[1] An NDC is an 11-digit identifier that indicates the manufacturer, the product dosage form, and the package size of a drug.

[2] CMS established the HCPCS to provide a standardized coding system for describing the specific items and services provided in the delivery of health care.

Section 1847A(d)(2)(B) of the Social Security Act (the Act) mandates that OIG compare ASPs with AMPs.[3] Pursuant to section 1847A(d)(3) of the Act, the Secretary of the Department of Health and Human Services may disregard the ASP for a drug or biological that exceeds the AMP for the product by at least 5 percent.

For this inspection, we obtained CMS's volume-weighted ASPs for the first quarter of 2005, which it calculated based on data submitted by manufacturers for the third quarter of 2004. We also obtained AMP data from CMS from the third quarter of 2004. We used these AMP data to calculate volume-weighted AMPs using both CMS's and OIG's methods. Ultimately, we compared volume-weighted ASPs to volume-weighted AMPs for 364 HCPCS codes, and identified codes for which the ASP exceeded the AMP by at least 5 percent according to either CMS's calculation or OIG's calculation.

FINDING

ASPs for certain HCPCS codes exceeded AMPs by at least 5 percent; however, the HCPCS codes that met the threshold differed depending on the method used to calculate volume-weighted ASP and AMP. Based on our analysis of data from the third quarter of 2004, a total of 51 HCPCS codes had an ASP that exceeded the AMP by at least 5 percent as a result of CMS's calculation. However, according to OIG's method for calculating volume-weighted ASPs and AMPs, only 38 HCPCS codes met the 5-percent threshold.

For 34 HCPCS codes, the volume-weighted ASPs exceeded the volume-weighted AMPs by at least 5 percent regardless of whether CMS's or OIG's calculation was used. An additional 4 HCPCS codes met the 5-percent threshold using OIG's calculation but not CMS's calculation. Another 17 HCPCS codes met the 5-percent threshold using CMS's calculation but not OIG's calculation.

SUMMARY

For the purpose of monitoring new prices based on ASPs, sections 1847A(d)(2)(B) and 1847A(d)(3) of the Act mandate that OIG perform comparisons between ASPs and AMPs to identify drugs for which the ASP exceeds the AMP by at least 5 percent. This review is the first of

[3]CMS collects AMPs as part of its Medicaid rebate agreements with manufacturers and as required by section 1927 of the Act.

such comparisons. We found that certain HCPCS codes did, in fact, meet the 5-percent threshold specified in the Act. However, the number of codes that met the threshold, and the monetary differences between ASPs and AMPs for those codes, depended on the method used to calculate volume-weighted ASPs and volume-weighted AMPs. Although 34 HCPCS codes met the 5-percent threshold regardless of whether CMS's or OIG's calculation was used, other codes only met the threshold using one calculation or the other.

Pursuant to section 1847A(d)(3) of the Act, the Secretary has authority to lower the reimbursement amount for a drug with an ASP that exceeds the AMP by the 5-percent threshold. Therefore, differences between the results of CMS's calculation and OIG's calculation could affect whether published reimbursement amounts for certain Medicare Part B drugs are adjusted. This, in turn, affects manufacturers, providers, and Medicare beneficiaries. It is therefore critical that CMS modify its calculation as soon as possible, both to ensure that reimbursement amounts are calculated correctly and to ensure that future comparisons between ASPs and AMPs yield the most meaningful results.

AGENCY COMMENTS

Overall, CMS indicated that the information in our report is helpful in its continuing efforts to monitor payment adequacy under the ASP methodology. However, CMS noted that OIG's review was conducted using data submitted during the initial implementation phase of the ASP methodology. According to CMS, much of the estimated savings identified in the report did not persist in subsequent quarters, and payment limits for many codes have since been revised.

Although CMS acknowledges the Secretary's authority to adjust the ASP payment limits when certain conditions are met, it believes that other issues should be considered, including the timing and frequency of pricing comparisons, stabilization of ASP reporting, the effective date and duration of rate substitution, and the accuracy of the ASP and AMP data.

OFFICE OF INSPECTOR GENERAL RESPONSE

This report found that comparisons between ASPs and AMPs yield different results depending on the method used to calculate volume-weighted ASPs and volume-weighted AMPs. Although CMS indicated

that our report is helpful, CMS's comments on the draft report addressed neither the incorrect calculation nor the impact that it has on the comparison between ASPs and AMPs. We continue to believe that CMS is calculating volume-weighted ASPs incorrectly, and that this incorrect calculation results in reimbursement amounts that are inaccurate and inconsistent with the ASP payment methodology set forth in section 1847A(b) of the Act. Furthermore, we believe that the incorrect calculation affects the results of mandated comparisons between ASPs and AMPs, and could continue to do so in the future.

We acknowledge CMS's concern that our findings should be examined in light of other important considerations. However, we are unsure of what, if any, specific steps CMS plans to take as a result of the report.

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INTRODUCTION

OBJECTIVE

To determine whether average sales prices (ASP) for individual Medicare Part B prescription drugs exceed average manufacturer prices (AMP) by at least 5 percent.

BACKGROUND

Medicare Part B Coverage of Prescription Drugs

Medicare Part B covers only a limited number of outpatient prescription drugs. Covered drugs include injectable drugs administered by a physician; certain self-administered drugs, such as oral anticancer drugs and immunosuppressive drugs; drugs used in conjunction with durable medical equipment; and some vaccines.

Medicare Part B Payments for Prescription Drugs

The Centers for Medicare & Medicaid Services (CMS) contracts with private companies, known as carriers, to process and pay Medicare Part B claims, including those for prescription drugs. Claims for drugs that are used with medical equipment are typically processed by one of four durable medical equipment regional carriers (DMERC). Claims for other types of covered drugs are processed by local carriers. To obtain reimbursement for covered outpatient prescription drugs, physicians and suppliers submit claims using procedure codes that are associated with covered drugs. CMS established the Healthcare Common Procedure Coding System (HCPCS) to provide a standardized coding system for describing the specific items and services provided in the delivery of health care. Each HCPCS code for outpatient prescription drugs defines the drug name and dosage size but does not specify manufacturer information or package size data.

Expenditures for Part B drugs have tripled over the past several years, increasing from approximately $3.3 billion in 1998 to over $10 billion in 2004. Although Medicare covers over 550 outpatient prescription drug HCPCS codes, the majority of spending for Part B drugs is concentrated on a relatively small subset of those codes. In 2004, 43 codes represented 90 percent of the expenditures for Part B drugs, with only 9 of these drugs representing half of the total Part B drug expenditures.

INTRODUCTION

Reimbursement Methodology for Part B Drugs and Biologicals in 2005

In 2005, Medicare began paying for most drugs using an entirely new methodology based on ASPs.[1] Section 1847A(c) of the Social Security Act (the Act), as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108-173, defines an ASP as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions such as volume discounts, prompt pay discounts, and cash discounts; free goods contingent on purchase requirements; chargebacks; and rebates other than those obtained through the Medicaid drug rebate program. Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" in the Medicaid drug rebate program.[2,3]

Manufacturers report ASPs by national drug codes (NDC), which are 11-digit identifiers that indicate the manufacturer of the drug, the product dosage form, and the package size. Manufacturers must provide CMS with the ASP and volume of sales for each NDC on a quarterly basis, with submissions due 30 days after the close of each quarter.[4]

Given that Medicare reimbursement for outpatient drugs is based on HCPCS codes rather than NDCs, and that more than one NDC may meet the definition of a particular HCPCS code, CMS has developed a file that "crosswalks" manufacturers' NDCs to HCPCS codes. CMS uses information in this crosswalk to calculate volume-weighted ASPs for covered HCPCS codes.

Third-quarter 2004 ASP submissions from manufacturers served as the basis for first-quarter 2005 Medicare allowances for most covered drug codes. Under the ASP pricing methodology, the Medicare allowance for

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[1] For 2004, the reimbursement amount for most covered drugs was based on 85 percent of the average wholesale price (AWP) as published in national pricing compendia such as the "Red Book." Prior to 2004, Medicare Part B reimbursed for covered drugs based on the lower of either the billed amount or 95 percent of the AWP.

[2] Pursuant to section 1927(c)(1)(C)(i) of the Act, "best price" is the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, with certain exceptions.

[3] Section 1847A(c) of the Act.

[4] Section 1927(b)(3) of the Act.

most Part B drugs is equal to 106 percent of the ASP for the HCPCS code. Medicare beneficiaries are responsible for 20 percent of this amount in the form of coinsurance.

The Medicaid Drug Rebate Program and AMPs

In order for Federal payment to be available for outpatient drugs covered under Medicaid, sections 1927(a)(1) and (b)(1) of the Act mandate that drug manufacturers enter into rebate agreements with the Secretary of the Department of Health and Human Services (Secretary) and pay quarterly rebates to State Medicaid agencies. Under these rebate agreements, and pursuant to section 1927(b)(3) of the Act, manufacturers must provide CMS with the AMP for each of their NDCs on a quarterly basis. As defined in section 1927(k)(1) of the Act, the AMP is the average unit price paid to the manufacturer by wholesalers in the United States for drugs distributed to the retail pharmacy class of trade, minus customary prompt pay discounts. The AMP is calculated as a weighted average of prices for all of a manufacturer's package sizes of a drug sold during a given quarter, and is reported for the lowest identifiable quantity of the drug (e.g., 1 milligram, 1 milliliter, one tablet, one capsule).

Office of Inspector General's Monitoring of ASPs and AMPs

Section 1847A(d)(2)(B) of the Act mandates that the Office of Inspector General (OIG) compare ASPs with AMPs. If OIG determines that the ASP for a drug exceeds the AMP by at least 5 percent, the Secretary has authority to substitute the payment amount for that drug product with 103 percent of the AMP for the drug.[5]

Related Work by the Office of Inspector General

Section 303(c)(3) of MMA also mandated that OIG determine whether physician practices in the specialties of hematology, hematology/oncology, and medical oncology could obtain drugs and biologicals for the treatment of cancer patients at 106 percent of the ASP. OIG completed this study in September 2005 and issued the report, "Adequacy of Medicare Part B Drug Reimbursement to Physician Practices for the Treatment of Cancer Patients," (A-06-05-00024). According to this report, physician practices in the specialties of hematology, hematology/oncology, and medical oncology could generally purchase drugs for the treatment of cancer patients at or below the reimbursement rate established under the ASP payment methodology.

[5]Section 1847A(d)(3) of the Act.

Recently, OIG issued another report discussing the method CMS uses to calculate a reimbursement amount for a HCPCS code. This report will be described in greater detail in the Methodology.

METHODOLOGY

We obtained CMS's volume-weighted ASPs for the first quarter of 2005, which it calculated based on NDC-level data submitted by manufacturers for the third quarter of 2004. In addition, we obtained the file that CMS used to crosswalk NDCs to their corresponding HCPCS codes. Both the volume-weighted ASPs and the crosswalk file were updated as of January 13, 2005. We also obtained AMP data from CMS for the third quarter of 2004.

Calculation of Volume-Weighted Average Sales Price

As mentioned previously, Medicare does not base reimbursement for covered drugs on NDCs; instead, it uses HCPCS codes. Therefore, CMS uses the ASP information submitted by manufacturers for each NDC to calculate a volume-weighted ASP for each covered HCPCS code. When calculating these volume-weighted ASPs, CMS only includes NDCs with ASP submissions that are deemed valid. We did not examine the NDCs that CMS opted to exclude from its calculation, nor did we verify the accuracy of CMS's crosswalk files.

As of January 13, 2005, CMS had established prices for 459 HCPCS codes based on the ASP reimbursement methodology. This total excludes HCPCS code J3490, which is defined as "unclassified drugs." Reimbursement amounts for the 459 HCPCS codes were based on ASP data for 2,399 NDCs.

To calculate the volume-weighted ASPs for these 459 codes, CMS used an equation that involves the following variables: the ASP for the NDC as reported by the manufacturer, the volume of sales for the NDC as reported by the manufacturer, and the number of billing units in the NDC as determined by CMS. The amount of the drug contained in an NDC may differ from the amount of the drug specified by the HCPCS code that providers use to bill Medicare. Therefore, the number of billing units in an NDC describes the number of HCPCS code units that are in that NDC. For instance, an NDC may contain a total of 10 milliliters of Drug A, but the corresponding HCPCS code may be defined as only 5 milliliters of Drug A. In this case, there are two billing units in the NDC. CMS calculates the number of billing units in each 11-digit NDC when developing its crosswalk files. A more detailed

description of CMS's method of calculating volume-weighted ASP is provided in Appendix A.

In a recent OIG report entitled "Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs" (OEI-03-05-00310), OIG stated that CMS's method for calculating volume-weighted ASP is incorrect because CMS does not use billing units consistently throughout its equation. As a result, many HCPCS codes have a reimbursement amount that is higher or lower than the amount that would have been calculated if billing units were used consistently. In the above-referenced report, OIG proposed an alternate equation that we believe uses billing units correctly. We used this equation to calculate an alternate volume-weighted ASP for each of the 459 HCPCS codes. To determine what the Medicare reimbursement amount would be according to OIG's calculation, we then multiplied OIG's volume-weighted ASPs for the 459 codes by 1.06. A more detailed description of OIG's calculation is presented in Appendix A.

Analysis of Average Manufacturer Price Data

An AMP is reported for the lowest identifiable quantity of the drug contained in the NDC (e.g., 1 milligram, 1 milliliter, one tablet, one capsule). In contrast, an ASP is reported for the entire amount of the drug contained in the NDC (e.g., for 50 milliliters, for 100 tablets). To ensure that the AMP would be comparable to the ASP, it was necessary to convert the AMP for each NDC so that it represented the total amount of the drug contained in that NDC.

In making these conversions, we examined AMPs only for those 2,399 NDCs that CMS used in its calculation of volume-weighted ASP for the 459 HCPCS codes. If AMP data were not available for one or more of these NDCs, we excluded the corresponding HCPCS code from our analysis. Ultimately, we excluded 80 HCPCS codes (718 NDCs). The other 379 HCPCS codes had AMP data for every NDC that CMS used in its calculation of volume-weighted ASPs. These 379 HCPCS codes represented 1,681 NDCs.

We then multiplied the AMPs for these 1,681 NDCs by the total amount of the drug contained in each NDC, as identified by sources such as the CMS crosswalk file, the "Red Book," manufacturer Web sites, and the Food and Drug Administration's NDC directory. We will refer to the resulting amounts as converted AMPs. For 27 NDCs, we could not successfully identify the amount of the drug reflected by the ASP and therefore could not calculate a converted AMP. These 27 NDCs were

crosswalked to 15 HCPCS codes. We did not include these 15 HCPCS codes (140 NDCs) in our final analysis.

Using the converted AMPs for the remaining 1,541 NDCs, we then calculated two different volume-weighted AMPs for each of the codes: one using the method that CMS used to calculate a volume-weighted ASP, and the other using the method that OIG used to calculate a volume-weighted ASP. We calculated volume-weighted AMPs for a total of 364 HCPCS codes. We did not verify the accuracy of manufacturer-reported ASP and AMP data.

Comparing Volume-Weighted ASPs to Volume-Weighted AMPs

For each of the 364 HCPCS codes included in our study, we then compared the volume-weighted ASPs and AMPs that resulted from CMS's calculation. We also compared the volume-weighted ASPs and AMPs that resulted from OIG's calculation. We identified codes with an ASP that exceeded the AMP by at least 5 percent according to either CMS's or OIG's calculation.

For those HCPCS codes that met or exceeded the 5-percent threshold, we conducted a review of the associated NDCs to verify the accuracy of the billing units information. According to our review, eight of the codes that met the 5-percent threshold had associated NDCs with potentially inaccurate billing units.[6] Given that volume-weighted ASPs and AMPs were calculated using this billing unit information, we could not be certain that the results for these eight codes were correct. Therefore, we did not include these eight codes in our findings.

For the remaining HCPCS codes, which both met the 5-percent threshold and had NDCs with accurate billing units, we then estimated the monetary impact of lowering reimbursement to 103 percent of the AMP.[7] For each of the HCPCS codes that met the 5-percent threshold using CMS's equation, we calculated 103 percent of CMS's volume-weighted AMP and subtracted this amount from the first-quarter 2005 reimbursement amount for the HCPCS code, which is equal to 106 percent of CMS's volume-weighted ASP. For each of the codes that met the 5-percent threshold using OIG's calculation, we subtracted

[6]NDCs for these eight codes had billing unit information in CMS's crosswalk file that may not have accurately reflected the number of billing units actually contained in the NDC.

[7]Pursuant to section 1847A(d)(3) of the Act, if OIG determines that the ASP for a drug exceeds the AMP by a threshold of 5 percent, the Secretary has authority to substitute the ASP-based payment with 103 percent of AMP.

103 percent of OIG's volume-weighted AMP from the alternate reimbursement amount for the HCPCS code (106 percent of OIG's volume-weighted ASP). We then multiplied the differences by the number of services that were allowed by Medicare for each HCPCS code in 2004, as reported in CMS's Part B Extract and Summary System (BESS).[8] This estimate assumes that the volume-weighted ASP for each HCPCS code will remain consistent throughout the year 2005. However, the ASP amounts submitted by manufacturers may actually vary from quarter to quarter.

To determine how the differences between OIG's and CMS's calculations might affect the results of the mandated comparison between ASPs and AMPs, we then compared the HCPCS codes that met the 5-percent threshold using CMS's calculation to the codes that met the threshold using OIG's calculation.

This study was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

[8]At the time of extraction, the BESS data were 96 percent complete for HCPCS codes processed by local carriers and 91 percent complete for HCPCS codes processed by the DMERCs.

FINDING

ASPs for certain HCPCS codes exceeded AMPs by at least 5 percent; however, the HCPCS codes that met the threshold differed depending on the method used to calculate volume-weighted ASPs and AMPs

Pursuant to sections 1847A(d)(2)(B) and 1847A(d)(3) of the Act, OIG must compare ASPs to AMPs and notify the Secretary if the ASP for a particular drug exceeds the AMP by a threshold of 5 percent. However, the HCPCS codes that meet this threshold may differ depending on whether CMS's method or OIG's method is used to calculate volume-weighted ASPs and volume-weighted AMPs. According to CMS's calculation, a total of 51 HCPCS codes had an ASP that exceeded the AMP by at least 5 percent in the third quarter of 2004. According to OIG's calculation, only 38 HCPCS codes met the 5-percent threshold.

The difference between CMS's calculation and OIG's calculation could also affect whether published reimbursement amounts for Medicare Part B drugs are adjusted. Sections 1847A(d)(3)(A) and (B) of the Act grant the Secretary authority to disregard the ASP pricing methodology for a drug with an ASP that exceeds the AMP by at least 5 percent. If that criterion is met, the Secretary has authority to lower the reimbursement amount for the drug to 103 percent of the AMP.[9] If reimbursement amounts for the 51 HCPCS codes identified by CMS's calculation had been lowered to 103 percent of the AMP, Medicare allowances would have been reduced by an estimated $164 million in 2005. Although fewer HCPCS codes met the 5-percent threshold using OIG's calculation, lowering the reimbursement amounts for those 38 codes would have actually reduced Medicare allowances by a greater amount—an estimated $172 million in 2005.

As shown in Table 1, some HCPCS codes met the 5-percent threshold regardless of whether CMS's or OIG's calculation was used. Other codes only met the 5-percent threshold according to one calculation or the other.

[9]Section 1847A(d)(3)(C) of the Act.

Table 1: Results of the Comparison Between ASPs and AMPs Using CMS's and OIG's Calculations

	Number of HCPCS Codes	Reduction in Reimbursement (in millions)
Met 5-percent threshold According to CMS's Calculation	**51**	**$164**
Met Threshold According to Both CMS's and OIG's Calculations	34	$161
Met Threshold According to CMS's Calculation Only	17	$3
Met 5-percent threshold According to OIG's Calculation	**38**	**$172**
Met Threshold According to Both CMS's and OIG's Calculations	34	$169
Met Threshold According to OIG's Calculation Only	4	$3

For 34 HCPCS codes, the volume-weighted ASPs exceeded the volume-weighted AMPs by at least 5 percent regardless of whether CMS's or OIG's calculation was used

According to our analysis, 34 HCPCS codes met the 5-percent threshold using either CMS's or OIG's calculation. However, the extent to which ASPs exceeded AMPs may have been different depending on which calculation was used.

For example, CMS's calculation for one HCPCS code resulted in a volume-weighted ASP of $4.82 and a volume-weighted AMP of $4.42. The difference between these two prices is 9 percent, which exceeds the 5-percent threshold specified in the Act. According to OIG's calculation for the same HCPCS code, the volume-weighted ASP should be $3.48 and the volume-weighted AMP should be $3.30. Here, the ASP exceeds the AMP by exactly 5 percent. Although this HCPCS code meets the 5-percent threshold regardless of which calculation is used, the prices themselves, and the percentage difference between those prices, can vary depending on whether CMS's or OIG's method is followed. This, in turn, could affect how much providers would receive in reimbursement, particularly if the reimbursement amount were lowered to 103 percent of the AMP.

According to CMS's calculation, lowering reimbursement for these 34 HCPCS codes to 103 percent of the AMP would have reduced Medicare allowances by an estimated $161 million in 2005. Using OIG's calculation for the same 34 codes, however, would have reduced Medicare allowances by an additional $8 million, for an estimated total of $169 million in 2005.

A list of all 34 HCPCS codes is presented in Appendix B.

FINDING

Four additional HCPCS codes met the 5-percent threshold using OIG's calculation but not CMS's calculation

For four HCPCS codes, the volume-weighted ASP exceeded the AMP by at least 5 percent using OIG's calculation but not CMS's calculation. If the reimbursement amounts for these four codes had been lowered to 103 percent of the AMP, we estimate that Medicare allowances would have been reduced by $2.7 million in 2005. These savings can be attributed almost entirely to one code, J0256.[10] A list of these four HCPCS codes is presented in Appendix C.

Another 17 HCPCS codes met the 5-percent threshold using CMS's calculation but not OIG's calculation

For 17 HCPCS codes, the volume-weighted ASPs exceeded AMPs by at least 5 percent using CMS's calculation but not OIG's calculation. Lowering the reimbursement amounts for these 17 HCPCS codes to 103 percent of the AMP would have reduced Medicare allowances by an estimated $2.7 million in 2005. The vast majority of these savings can be attributed to three HCPCS codes: J3301, J1080, and J1550.[11] A list of all 17 HCPCS codes is presented in Appendix D.

[10] HCPCS code J0256 represents an injection of alpha 1-proteinase inhibitor–human, 10 milligrams (mg).

[11] HCPCS code J3301 represents an injection of triamcinolone acetonide, per 10 mg; HCPCS code J1080 represents an injection of testosterone cypionate, 1cc, 200 mg; and HCPCS code J1550 represents an injection of gamma globulin, intramuscular, 10 cc.

SUMMARY

For the purpose of monitoring new prices based on ASPs, sections 1847A(d)(2)(B) and 1847A(d)(3) of the Act mandate that OIG perform comparisons between ASPs and AMPs to identify drugs for which the ASP exceeds the AMP by at least 5 percent. This review is the first of such comparisons. We found that certain HCPCS codes did, in fact, meet the 5-percent threshold specified in the Act. However, the number of codes that met the threshold, and the monetary differences between the ASPs and AMPs for those codes, depended on the method used to calculate volume-weighted ASPs and volume-weighted AMPs. Although 34 HCPCS codes met the 5-percent threshold regardless of whether CMS's or OIG's calculation was used, other codes only met the threshold using one calculation or the other.

Pursuant to section 1847A(d)(3) of the Act, the Secretary has authority to lower the reimbursement amount for a drug with an ASP that exceeds the AMP by the 5-percent threshold. Therefore, differences between the results of CMS's calculation and OIG's calculation could affect whether published reimbursement amounts for certain Medicare Part B drugs are adjusted. This, in turn, affects manufacturers, providers, and Medicare beneficiaries. It is therefore critical that CMS modify its calculation as soon as possible, both to ensure that reimbursement amounts are calculated correctly and to ensure that future comparisons between ASPs and AMPs yield the most meaningful results.[12]

AGENCY COMMENTS

Overall, CMS indicated that the information in our report is helpful in its continuing efforts to monitor payment adequacy under the ASP methodology. However, CMS noted that OIG's review was conducted using data submitted during the initial implementation phase of the ASP methodology. According to CMS, much of the estimated savings

[12]Issues with CMS's calculation of volume-weighted ASP are discussed in greater detail in the OIG report, "Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs" (OEI-03-05-00310). This report found that CMS's method for calculating volume-weighted ASP is incorrect because CMS does not use billing units consistently throughout its equation. Therefore, OIG recommended that CMS adopt an alternate method for calculating volume-weighted ASP, which does use billing units consistently.

identified in the report did not persist in subsequent quarters, and payment limits for many codes have since been revised.

Although CMS acknowledges the Secretary's authority to adjust the ASP payment limits when certain conditions are met, it believes that other issues should be considered, including the timing and frequency of pricing comparisons, stabilization of ASP reporting, the effective date and duration of rate substitution, and the accuracy of the ASP and AMP data.

The full text of CMS's comments can be found in Appendix E.

OFFICE OF INSPECTOR GENERAL RESPONSE

This report found that comparisons between ASPs and AMPs yield different results depending on the method used to calculate volume-weighted ASPs and volume-weighted AMPs. Although CMS indicated that our report is helpful, CMS's comments on the draft report addressed neither the incorrect calculation nor the impact it has on the comparison between ASPs and AMPs. We continue to believe that CMS is calculating volume-weighted ASPs incorrectly, and that this incorrect calculation results in reimbursement amounts that are inaccurate and inconsistent with the ASP payment methodology set forth in section 1847A(b) of the Act. Furthermore, we believe that the incorrect calculation affects the results of mandated comparisons between ASPs and AMPs, and could continue to do so in the future.

We acknowledge CMS's concern that our findings should be examined in light of other important considerations. However, we are unsure of what, if any, specific steps CMS plans to take as a result of the report.

APPENDIX - A

Equations Used by CMS and OIG to Calculate Volume-Weighted ASPs and AMPs

1. The Equation Used by CMS to Calculate a Volume-Weighted ASP

In the following equation, a "unit" is defined as the entire amount of the drug contained in the NDC:

$$\text{Volume-Weighted ASP for the Billing Unit of HCPCS Code} = \frac{\text{Sum of } \left[\frac{\text{ASP for NDC}}{\text{Billing Units in NDC}} * \text{Number of NDCs Sold} \right]}{\text{Sum of Number of NDCs Sold}}$$

2. The Equation Used by OIG to Calculate a Volume-Weighted ASP

We suggest that CMS's calculation should be modified by multiplying the number of NDCs sold by the number of billing units in the NDC in both the numerator and denominator of the equation:

$$\text{Volume-Weighted ASP for the Billing Unit of HCPCS Code} = \frac{\text{Sum of } \left[\frac{\text{ASP for NDC}}{\text{Billing Units in NDC}} * \text{Number of NDCs Sold} * \text{Billing Units in NDC} \right]}{\text{Sum of (Number of NDCs Sold} * \text{Billing Units in NDC)}}$$

However, the terms "Billing Units in NDC" in the numerator of the equation cancel each other out:

$$\text{Volume-Weighted ASP for the Billing Unit of HCPCS Code} = \frac{\text{Sum of } \left[\frac{\text{ASP for NDC}}{\cancel{\text{Billing Units in NDC}}} * \text{Number of NDCs Sold} * \cancel{\text{Billing Units in NDC}} \right]}{\text{Sum of (Number of NDCs Sold} * \text{Billing Units in NDC)}}$$

Therefore, OIG's equation is written in the following way:

$$\text{Volume-Weighted ASP for the Billing Unit of HCPCS Code} = \frac{\text{Sum of (ASP for NDC} * \text{Number of NDCs Sold)}}{\text{Sum of (Number of NDCs Sold} * \text{Billing Units in NDC)}}$$

APPENDIX ~ B

Thirty-Four HCPCS Codes With an ASP That Exceeded the AMP by at Least 5 Percent Regardless of Whether CMS's or OIG's Calculation Was Used

Code	Description
J0360	Injection, hydralazine HCl, up to 20 mg
J0470	Injection, dimercaprol, per 100 mg
J0770	Injection, colistimethate sodium, up to 150 mg
J1110	Injection, dihydroergotamine mesylate, per 1 mg
J1180	Injection, dyphylline, up to 500 mg
J1240	Injection, dymenhydrinate, up to 50 mg
J1250	Injection, dobutamine, HCl, per 250 mg
J1364	Injection, erythromycin lactobionate, per 500 mg
J1940	Injection, furosemide, up to 20 mg
J1955	Injection, levocarnitine, per 1 g
J2324	Injection, nesiritide, 0.25 mg
J2501	Injection, paricalcitol, 1 mcg
J2545	Pentamidine isethionate, inhalation solution, per 300 mg
J2675	Injection, progesterone, per 50 mg
J2690	Injection, procainamide HCl, up to 1 g
J2730	Injection, pralidoxime chloride, up to 1 g
J3364	Injection, urokinase, 5,000 IU vial
J3365	Injection, IV, urokinase, 250,000 IU vial
J3415	Injection, pyridoxine HCl, 100 mg
J3487	Injection, zoledronic acid, 1 mg
J7517	Mycophenolate mofetil, oral, 250 mg
J7644	Ipratropium bromide, inhalation solution administered through DME, unit dose form, per mg
J9060	Cisplatin powder or solution, per 10 mg
J9185	Fludarabine phosphate, 50 mg
J9202	Goserelin acetate implant, per 3.6 mg
J9219	Leuprolide acetate implant, 65 mg
J9300	Gemtuzumab ozogamicin, 5 mg
J9320	Streptozocin, 1 g
J9360	Vinblastine sulfate, 1 mg
J9370	Vincristine sulfate, 1 mg
J9375	Vincristine sulfate, 2 mg
J9380	Vincristine sulfate, 5 mg
Q0164	Prochlorperazine maleate, 5 mg, oral
Q0175	Perphenazine, 4 mg, oral

Source: OIG Analysis of the ASP and AMP Data, 2005.

APPENDIX ~ C

Four HCPCS Codes With an ASP That Exceeded the AMP by at Least 5 Percent Using OIG's Calculation but not CMS's Calculation

Code	Description
J0256	Injection, alpha 1-proteinase inhibitor – human, 10 mg
J1790	Injection, droperidol, up to 5 mg
J2993	Injection, reteplase, 18.1 mg
Q0178	Hydroxyzine pamoate, 50 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen

Source: OIG Analysis of the ASP and AMP Data, 2005.

APPENDIX - D

Seventeen HCPCS Codes With an ASP That Exceeded the AMP by at Least 5 Percent Using CMS's Calculation but not OIG's Calculation

Code	Description
J1080	Injection, testosterone cypionate, 1 cc, 200 mg
J1460	Injection, gamma globulin, intramuscular, 1 cc
J1470	Injection, gamma globulin, intramuscular, 2 cc
J1480	Injection, gamma globulin, intramuscular, 3 cc
J1490	Injection, gamma globulin, intramuscular, 4 cc
J1500	Injection, gamma globulin, intramuscular, 5 cc
J1510	Injection, gamma globulin, intramuscular, 6 cc
J1520	Injection, gamma globulin, intramuscular, 7 cc
J1530	Injection, gamma globulin, intramuscular, 8 cc
J1540	Injection, gamma globulin, intramuscular, 9 cc
J1550	Injection, gamma globulin, intramuscular, 10 cc
J1560	Injection, gamma globulin, intramuscular, over 10 cc
J1630	Injection, haloperidol, up to 5 mg
J1885	Injection, ketorolac tromethamine, per 15 mg
J3301	Injection, triamcinolone acetonide, per 10 mg
J3410	Injection, hydroxyzine HCl, up to 25 mg
J3420	Injection, vitamin B-12 cyanocobalamin, up to 1,000 mcg

Source: OIG Analysis of the ASP and AMP Data, 2005.

APPENDIX E

Comments from the Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

JAN - 6 2006

TO: Daniel R. Levinson
Inspector General

FROM: Mark B. McClellan, M.D., Ph.D.
Administrator

SUBJECT: Office of the Inspector General (OIG) Draft Report: "Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Price to Average Manufacturer Price" (OEI-03-04-00430)

Thank you for the opportunity to review and comment on the Office of Inspector General's (OIG) draft report entitled, "Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Price to Average Manufacturer Price." We appreciate the OIG's efforts in examining this issue.

The OIG report compares manufacturers' reported drug prices under the Medicare and Medicaid programs for the third calendar quarter of 2004 to identify drug billing codes for which the volume weighted average sale price (ASP) exceeds the volume weighed average manufacturer price (AMP) by at least 5 percent. The OIG found that for certain billing codes the ASP payment limit exceeds the volume weighted AMP by 5 percent. The number of billing codes identified and the monetary differences between the ASPs and AMPs for those billing codes depends on the method used to calculate the volume weighted average prices.

The OIG's review was conducted using data submitted during the initial implementation phase of the ASP methodology. The Centers for Medicare & Medicaid Services (CMS) continues to work with manufacturers to improve ASP and AMP reporting consistency. We reviewed the OIG's findings and note that half of the estimated savings is attributable to one product for which the AMP varied significantly from subsequent periods. We also found that over 92 percent of the estimated savings do not persist in comparing ASP and AMP data from subsequent quarters. Furthermore, CMS revised the first quarter 2005 payment limits for several of the identified billing codes. In addition, earlier this year, we addressed a data conversion issue that impacted J0256 as well as a majority of the billing codes listed in Appendix D. These changes are evidence of our continued progress in refining ASP calculations.

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While the Secretary has authority to adjust the ASP payment limit when certain conditions are met, we believe it is important to bear in mind timing, stabilization of ASP reporting, and other important considerations as we further examine the findings of this report. Other issues for consideration include future timing and frequency of ASP and AMP comparisons, effective date and duration of the rate substitution, and evaluation of the accuracy of ASP and AMP data.

Thank you very much for your work on this report. The information it contains is helpful in our efforts to monitor payment adequacy under the new ASP methodology.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and Linda M. Ragone, Deputy Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

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